Supreme Court, U.S.
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No. 97-26

In The

Supreme Court of the United States

October Term, 1996

DEBORAH EDDY AND EDDY,

Petitioners,

v.

POLYMER TECHNOLOGY CORPORATION,
THRIFT DRUG, INC. AND
DR. JAMES H. LETHAM, O.D.,

Respondents.

On Petition For A Writ Of Certiorari To The Superior Court Of Pennsylvania

PETITIONERS' REPLY MEMORANDUM

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A. The Basis of the Pennsylvania Superior Court's Judgment Is Readily Ascertainable.

The ruling of the Pennsylvania Superior Court was expressly predicated on that court's belief that pre-market approval ("PMA") by the Food and Drug Administration ("FDA") preempts all of Petitioners' state law causes of action.[1] Inability to ascertain the reasons for the Pennsylvania Supreme Court's denial of discretionary review is beside the point, as it is the decision of the Superior Court for which *certiorari* is sought.

B. The FDA Did Not "Require" Respondents Not to Warn of the Danger of Acanthamoeba Keratitis Infection from Tap Water Rinsing.

Respondents' principal argument is that the Superior Court's decision is consistent with the reasoning of *Medtronic, Inc. v. Lohr*,[2] and with the holdings of post-*Medtronic* PMA cases, because this case "involves a direct conflict between the defect claimed by Petitioners – tap water rinsing is dangerous – and the labeling required by the FDA – tap water rinsing is proper." Brief

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[1] The Superior Court explained: "a finding in favor of [appellants] on any of their alleged state tort law claims would impose additional or different requirements on [appellee] . . . whose product . . . has already received FDA approval. Such requirements are in conflict with the MDA and thus, the [appellants'] state law claims are therefore preempted." App. 4-5, quoting *Green v. Dolsky*, 641 A.2d 600, 605 (Pa. Super. 1994), *aff'd*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 2579 (1997) (brackets and ellipses in original).

[2] 116 S. Ct. 2240 (1996).

of Respondents at 4. This argument is wrong, for two reasons.

First, the FDA did not *require* the labeling at issue; it merely *approved* labeling designed and submitted by Respondent Polymer. The absence of an affirmative federal requirement renders this case starkly different from the tampon / toxic shock syndrome ("TSS") cases with which Respondents would group it. Thus, in *Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997), the Ninth Circuit found state law mislabeling claims preempted because the FDA had "promulgated a regulation mandating the specific substantive content of the TSS warnings on tampon boxes and/or tampon package inserts." *Id.* at 740, citing 21 C.F.R. 801.430. The presence of such a specific, mandatory, substantive regulation made the case one "in which the Federal Government has weighed the competing interests . . . and implemented [its] conclusion via a specific mandate on manufacturers or producers." *Id.* at 741, quoting *Medtronic*, 116 S. Ct. at 2258.[3]

In contrast to the FDA's direct regulation of the substance of the warning at issue in *Papike*, in the present case the FDA did not affirmatively mandate or require the content of the labeling chosen by Polymer. It is instructive that the Ninth Circuit considered the specificity of the tampon labeling regulation to be the factor

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[3] *Cf. Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (finding limited statutory preemption where statute specified precise warning to be included with cigarettes).

that distinguished *Papike* from its prior holding in *Kennedy v. Collagen Corp.*[4] that the FDA's premarket approval process is *not* a "specific requirement applicable to a particular device."[5] Because the present case involves only premarket approval rather than an affirmative regulatory requirement, it is unlike the tampon cases but indistinguishable from *Kennedy* and the state court PMA cases cited in Petitioners' Petition for Writ of Certiorari.

Second, even if the FDA's approval somehow transformed Polymer's designs into federal requirements, no aspect of that approval required Respondents not to provide warnings or information regarding the risk of acanthamoeba keratitis infection. Indeed, the FDA's regulations expressly permit a manufacturer of an approved Class III medical device to make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction" without prior FDA approval. 21 C.F.R. § 814.39(d)(i). Petitioner has claimed that Respondents had a duty under Pennsylvania tort law to supply warnings and information about

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[4] 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 2579 (1996).

[5] "FDA regulations . . . provide that state requirements are pre-empted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 CFR 808.1(d) (1995)." *Medtronic*, 116 S. Ct. at 2257. *Cf. Committee of Dental Amalgam Manufacturers & Distributors v. Stratton*, 92 F.3d 807, 813 (9th Cir. 1996), cert. denied, 117 S. Ct. 754 (1997) ("Inherent in the term "requirement" is the idea that there be a positive enactment from the FDA before preemption can be triggered.").

an adverse reaction,[6] and the applicable federal regulation allows labeling changes which would comply with that duty. Respondents' conclusion that "[j]oint compliance [with state law duties and FDA requirements] is impossible", Brief of Respondents at 10, is simply wrong.

C. This Case Raises a Recurring Issue with Important Implications for state Product Liability Law.

Respondents suggest that despite the conflict among State courts with respect to the preemptive effect of premarket approval, this Court should deny review "until the federal courts of appeal in which these courts are located have looked at the issue". Brief of Respondents at 14 n.4. However, although the MDA is a federal statute, issues concerning its preemptive effect are likely to arise more frequently in state courts than in federal courts. Most tort claims arise under state law, and because plaintiffs in product liability cases usually join local distributors or suppliers as defendants (as in this case), the federal courts have neither federal question nor diversity jurisdiction over such claims.

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[6] Respondents incorrectly assert that "Petitioners claim only one defect in the contact lens Solution and Cleaner: labeling which permits 'tap water rinsing' makes the product unsafe and defective." Brief of Respondents at 9. On the contrary, Petitioners alleged in their complaint, *inter alia*, that "the lens cleaner and the conditioning solution . . . were in a defective condition because of the lack of warning and information to accompany these products." Complaint ¶ 18 (R. 9a).

The PMA preemption issue is no less weighty because it has been addressed in state courts. The displacement of important state law product safety and compensation policies[7] implicates concerns which are central to our federal system.

Respectfully submitted,

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[7] The importance of PMA preemption as a concern of state law is illustrated by the joinder of a majority of the States as *Amici Curiae* in support of petitions for *certiorari* in two previous cases presenting the same issue. *See* Brief of Alabama, et al. in *King v. Collagen Corp.*, No. 92-1979 and in *Stamps v. Collagen Corp.*, No. 92-1989.